K132492

510(k) SUMMARY

SEP 05 2013

SUBMITTED BY: Mari Meyer
Director, Regulatory Affairs
DiaSorin Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285
Phone (651) 439-9710
Fax (651) 351-5669
Email: mari.meyer@diasorin.com

DATE PREPARED: August 28, 2013

PURPOSE OF SUBMISSION: New Device

NAME OF DEVICE:

Trade Name: LIAISON® 25 TOTAL-D
LIAISON® 25 TOTAL-D Control Set
LIAISON® 25 TOTAL-D Calibration Verifiers

Common Names/Descriptions: Vitamin D

Classification Names: Vitamin D Test System: Class II
21 CFR 862.1825; Clinical Chemistry (75)
Quality Control Material: Class I, reserved
21 CFR 862.1660; Clinical Chemistry (75)

Product Code: MRG, JJX

PREDICATE DEVICE: LIAISON® 25 OH Vitamin D TOTAL
K112725
LIAISON® 25 OH Vitamin D Control
K112725
LIAISON® 25 OH Vitamin D Calibration
Verifier K090104

DEVICE DESCRIPTION:
The LIAISON® 25 TOTAL-D consists of one Reagent Intergral with calibrators, which consists of:

Magnetic Particles (2.4 mL)	Magnetic particles coated with goat antibody against 25 OH Vitamin D, protein, phosphate buffer, < 0.1% sodium azide.
Assay Buffer (28.0 mL)	Buffer with 7.5% ethanol, surfactants and 0.2% ProClin® as a preservative.
Conjugate (4.5 mL)	25 OH Vitamin D conjugated to an isoluminol derivative, in phosphate buffer with10% ethanol, EDTA and 0.1%

	benzoic acid as a preservative.
Calibrator 1 (1.2 mL)	Human serum, BSA, <0.1% sodium azide and 25 OH Vitamin D. The calibrator concentrations (ng/mL) are referenced to standard preparations containing highly purified 25 OH Vitamin D.
Calibrator 2 (1.2 mL)	Human serum, BSA, <0.1% sodium azide and 25 OH Vitamin D. The calibrator concentrations (ng/mL) are referenced to standard preparations containing highly purified 25 OH Vitamin D.

ProClin® 300 is a registered trademark of Rohm and Haas Co.

The LIAISON® 25 TOTAL-D control consists of 2 levels of human serum, BSA, <0.1% sodium azide and 25 OH Vitamin D.

The LIAISON® 25 TOTAL-D calibration verifier consists of 4 levels of human serum, BSA, <0.1% sodium azide and 25 OH Vitamin D.

INTENDED USE:

The LIAISON® 25 TOTAL-D assay is a chemiluminescent immunoassay (CLIA) intended for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites in human serum, EDTA and Lithium heparin plasma. The LIAISON® 25 TOTAL-D assay is to be used as an aid in the assessment of vitamin D sufficiency in adults. The DiaSorin LIAISON® 25 TOTAL-D is intended to be used on the LIAISON® XL Analyzer.

The DiaSorin LIAISON® 25 TOTAL-D Control Set is intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® 25 TOTAL-D assay.

The DiaSorin LIAISON® 25 TOTAL-D Calibration Verifiers are assayed quality control materials intended for use in the quantitative verification of calibration and reportable range of the LIAISON® 25 TOTAL-D assay when performed on the LIAISON® XL Analyzer.

TEST PRINCIPLE:

The DiaSorin LIAISON® 25 TOTAL-D assay is a direct competitive chemiluminescence immunoassay (CLIA) for quantitative determination of 25 OH vitamin D in human serum or plasma. During the first incubation, 25 OH vitamin D is dissociated from its binding protein and binds to the specific antibody on the solid phases. After 10 minutes the tracer, (vitamin D linked to an isoluminol derivative) is added. After a second 10 minute incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added to initiate a flash chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLU) and is inversely proportional to the concentration of 25 OH vitamin D present in calibrators, controls, or samples.

COMPARISON TO PREDICATE DEVICE:

The DiaSorin LIAISON® 25 TOTAL-D assay is substantially equivalent in principle and performance to the LIAISON® 25 OH Vitamin D TOTAL assay (K112725) which was FDA cleared January 20, 2012.

Table 1: Summary of Device Similarities - LIAISON® 25 TOTAL-D		
Characteristic	**New Device LIAISON® 25 TOTAL-D**	**Predicate Device LIAISON® 25 OH Vitamin D TOTAL assay (K112725)**
Intended Use	*In-vitro* assay for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites.	*In-vitro* assay for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites.
Indications for Use	To be used as an aid in the assessment of vitamin D sufficiency in adults.	Same
Measured Analyte	25-hydroxyvitamin D	Same
Assay Type	Chemiluminescent Immunoassay	Same
Test principle	Competitive chemiluminescent Immunoassay	Same
Solid Support	Paramagnetic particles coated with goat antibody against 25 OH Vitamin D	Same
Reagent Integral Storage	On-board or in refrigerator@ 2-8°C	Same
Sample Handling/Processing	Automated	Same
Unit of Measure	ng/mL	Same
Calibration	Two-point calibrator verification of stored master curve. Included with the kit.	Same
Measuring range	4 – 150 ng/mL	Same
Conjugate Antibody	25 OH Vitamin D conjugated to an isoluminol derivative	Same
Controls	2 Levels	Same
Open storage 2-8°C	4 weeks	Same

Table 2 : Summary of Device Differences - LIAISON® 25 TOTAL-D		
Characteristic	**New Device LIAISON® 25 TOTAL-D**	**Predicate Device LIAISON® 25 OH Vitamin D TOTAL assay (k112725)**
Sample Matrix	Human serum, EDTA and Li heparin plasma	Human serum
Sample size	15 uL	25 uL
Calibration Matrix	Human serum with BSA and, sodium azide	Human serum with buffer salts and sodium azide.

The DiaSorin LIAISON® 25 TOTAL-D Control is substantially equivalent in principle and performance to the LIAISON® 25 OH Vitamin D TOTAL Control (K112725) which was FDA cleared January 20, 2012.

Table 3: Summary of Device Similairites and Difference LIAISON® 25 TOTAL-D Control Set		
Characteristic	**LIAISON® 25 TOTAL-D Control**	**LIAISON® 25 OH Vitamin D TOTAL Control (K112725)**
Intended Use	Intended for use as assayed quality control samples to monitor the accuracy and precision of the assay.	Same
Storage	Store at 2-8°C until ready to use	Same
Matrix	Human serum with BSA and, sodium azide	Human serum with buffer salts and sodium azide.
Levels	2 levels: low and high	Same

The DiaSorin LIAISON® 25 TOTAL-D Calibration Verifiers are substantially equivalent in principle and performance to the LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers (K090104) which were FDA cleared September 9, 2009.

Table 4: Summary of Device Similarities and Differences LIAISON® 25 TOTAL-D Calibration Verifiers		
Characteristic	**LIAISON® 25 TOTAL-D Calibration Verifiers**	**LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers (K090104)**
Intended Use	Assayed quality control materials for *in vitro* diagnostic use in the quantification verification of calibration and reportable range of the DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay.	Same
Product Storage	2 to 8°C	Same
Matrix	Human serum with BSA and, sodium azide	Human serum with buffer salts and sodium azide.
Levels	Four	Same
Volume	5.0 mLs	Same

PERFORMANCE DATA:

Method Comparison:

A method comparison study was performed on 403 serum samples following CLSI EP9-A2. The samples were tested in singlicate by both the LIAISON® 25 TOTAL-D assay and the predicate device. Testing for the LIAISON® 25 TOTAL-D assay and the predicate assay was performed at DiaSorin according to the respective Instructions for Use. All specimens were stored at -20°C or below until tested.

Samples tested in the method comparison included de-identified residual serum samples spanning the assay range which were obtained from a sample procurement organization. The samples are excess samples drawn from non-selected U.S. and/or European patients with sufficient volume to perform all testing required. Twenty-three (23) of the 403 samples were spiked or diluted samples in order to achieve sample values that reach the upper and/or lower limits of the assay range.

Three hundred ninety-one (391) of the 403 samples tested were analyzed. Twelve (12) samples read below the measuring range of the LIAISON® 25 TOTAL-D assay (<4.0 ng/mL) and therefore were not included in the analysis. Individual 25 OH Vitamin D results were plotted. Passing and Bablok regression analyses were performed for all samples across the measuring range of the assays.

Results

The range of the results observed with the LIAISON® 25 TOTAL-D assay ranged from 4.18 – 135 ng/mL. Passing & Bablok regression analysis was applied to these samples and is summarized in the following table.

Table 5: Method Comparison Passing & Bablok Regression Data

N	Slope (95%CI)	Intercept (95% CI)	Correlation Coefficient
391	0.99 (0.97-1.01)	-0.22 (-0.51-0.08)	0.990

Matrix comparison:

Serum, SST Serum, Lithium Heparin, EDTA Plasma

Sixty four (64) matched patient sets of serum, SST serum, lithium heparin plasma and EDTA plasma samples spanning the measuring range of the assay (4.0-139.3 ng/mL) were tested to determine if serum, SST serum, lithium heparin plasma and EDTA plasma samples provide equivalent results on the LIAISON® 25 TOTAL-D assay.

Results

A Passing-Bablok method comparison was used for analysis comparing each sample type separately to the corresponding serum samples, with the specification of a 0.90 to 1.10 slope to serum considered acceptable.

SST Serum Compared to Serum

	Bias	95% CI	
y-intercept	0.4098	-0.1694	to 1.1652
Slope	0.9942	0.9785	to 1.0113

EDTA Plasma Compared to Serum

	Bias	95% CI	
y-intercept	-0.5785	-1.1028	to -0.0976
Slope	1.0092	0.9916	to 1.0253

Lithium Heparin Plasma Compared to Serum

	Bias	95% CI	
y-intercept	-0.0211	-0.5554	to 0.4683
Slope	1.0007	0.9869	to 1.0180

Conclusion

The study shows equivalent testing results from SST serum, EDTA plasma or lithium heparin plasma to serum.

Reference Range/Expected Values:

A reference range study was performed in accordance with CLSI Guideline C28-A2. Participant enrollment took place at four sites in the contiguous US, representing a wide distribution of sun strength: northern, southern, and central US. The collection was conducted on adults (ages 21 – 90 years) in summer and winter, including light and

dark skin individuals, and males and females. Three hundred and ninety five (395) samples met the inclusion/exclusion criteria and were tested with the LIAISON® 25 TOTAL-D Assay.
The determination of apparently healthy for this study was based on the following definition:

- Normal serum levels of:
  - o Total calcium
  - o Intact parathyroid hormone (PTH)
  - o Thyroid stimulating hormone (TSH)
- No personal history of kidney, gastrointestinal or liver disease
- No personal history of parathyroid, thyroid, or chronic disease (defined by severity of condition which is linked to treatment and frequency as stated on subject's CRF)
- No personal history of seizures
- No bariatric surgery
- No family history of parathyroid or calcium regulatory disease

Other criteria were: at least 50% of subjects NOT taking ANY Vitamin D supplementation, and of the less than 50% of subject taking Vitamin D supplementation, level of supplementation must be <2000 IU/day. Subjects were not currently taking any medications known to affect absorption (drugs that inhibit cholesterol absorption) or increase catabolism, such as anticonvulsants, glucocorticoids, HAART (AIDS treatment) and anti-rejection medications

1. Current use of dietary or alternative therapies containing high concentrations of Vitamin D (e.g. adults ≥ 2,000 IU / day)
2. More than 50% of subjects are taking Vitamin D supplementation
3. Family history of parathyroid or calcium regulatory disease
4. Personal history of the following diseases: kidney, gastrointestinal, liver, thyroid, or parathyroid
5. Personal history of seizures
6. Bariatric surgery
7. Pregnancy or lactation

The Instructions for Use contain the following table and statement:
Reference Range

	Observed Reference Ranges	
Population (395)	Median 25 OH Vitamin D	Central 95% Interval
United States	22.9 ng/mL	8.8 ng/mL – 54.2 ng/mL

Consider these limits as guidelines only. It is important for each laboratory to establish its own reference range, representative of its typical population.

Reproducibility/Precision:
A twenty day reproducibility/precision study was performed at DiaSorin Inc consisting of a coded panel comprised of 6 frozen serum samples. The coded panel contained samples for each level of low, medium and high 25 OH Vitamin D medical decision concentrations. The LIAISON® 25 TOTAL-D controls (2 levels) were also tested in the study. The CLSI document EP5-A2 was followed in the preparation of the testing protocol.
The precision panel samples and kit controls were tested on the LIAISON® 25 TOTAL-D assay on 1 Reagent Integral lot at one site in two replicates per run, 2 runs per day for 20 operating days on 1 analyzer for a total of 80 replicate results per sample.

The mean, standard deviation, and coefficient of variation (%CV) of the results were computed for each of the tested specimens.

Results
The 20 day results obtained at DiaSorin Inc. are summarized in Table 5 as sample overall mean 25 OH Vitamin D concentration in ng/mL, computed SDs and %CVs for within run and total within lot.

Table 7: DiaSorin Inc. – 20 day Reproducibility/Precision

Sample ID	N	mean conc (ng/mL)	Within run		Total	
			SD	%CV	SD	%CV
KC 1	80	15.4	0.68	4.4%	1.78	11.6%
KC 2	80	52.8	1.57	3.0%	3.29	6.2%
Sample 1	80	11.2	0.43	3.8%	1.52	13.6%
Sample 2	80	17.7	0.56	3.1%	1.82	10.3%
Sample 3	80	28.2	0.80	2.9%	2.36	8.4%
Sample 4	80	34.3	1.03	3.0%	2.96	8.6%
Sample 5	80	65.1	1.35	2.1%	3.97	6.1%
Sample 6	80	113.5	2.27	2.0%	5.70	5.0%

Dilution Linearity:
A linearity study was performed using samples slightly above the upper measuring limit of the LIAISON® 25 TOTAL-D Assay, following CLSI EP6-A. Separate serum, SST (serum separator tubes), EDTA plasma and lithium heparin plasma pools that met this criterion were diluted with the assay's Specimen Diluent to yield multiple dilutions with Vitamin D levels spanning the assay's full measuring range of 4 – 150 ng/mL. Each dilution was analyzed in replicates of 4 with one lot of the modified Vitamin D Assay on one LIAISON® XL Analyzer.

Expected concentrations for the dilutions were determined by (Vitamin D value of high pool) x (dilution factor).

Results
The results for each sample were analyzed by linear regression (slope and, intercept) of observed 25 OH D concentrations versus expected 25 OH D concentrations in ng/mL.

The resulting equation for each sample type is:

Serum: y (observed) = 1.025x (expected) - 0.6094
SST serum: y (observed) = 1.0064x (expected) - 0.3887
EDTA plasma: y (observed) = 1.0092x (expected) - 0.4958
Lithium heparin plasma: y (observed) = 1.0421x (expected) - 0.8295

A polynomial regression fit of the serum data yielded statistically insignificant second and third order terms. These results support the claimed measuring range of 4 to 150 ng/mL.

LoB/LoD/LoQ:
The study was performed based upon CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline June 2012- Second Edition.

For LoB, 6 blank sample aliquots were tested in the LIAISON® 25 TOTAL-D assay on two analyzers, with two reagent lots and two technicians over six runs over three days yielding 60 concentration results.

For LoD, four (4) samples in the range of the mean LoB to 4 times the mean LoB were tested with the LIAISON® TOTAL-D on one LIAISON® XL Analyzer with two reagent lots and two technicians over six runs and three days (2replicates/sample/run) yielding a minimum of 96 concentration results.

For LoQ, eight (8) samples (4 of which were used in the LoD determination) in the range of approximately 1.5 ng/mL to approximately 5.3 ng/mL were tested in the LIAISON® 25 TOTAL-D assay on two LIAISON® XL Analyzer with two reagent lots and two technicians over six runs and three days (2 replicates/sample/run), yielding 192 concentration results to define LoQ. To verify the LoQ, the same 8 samples were run on 1 LIAISON® XL Analyzer with a third reagent lot and two technicians over four runs (3 replicates/sample/run) yielding 96 concentration results to verify LoQ.

Results:
The limits are reported in the following table:

LoB	LoD	LoQ
≤ 2.03 ng/mL	2.91 ng/mL	4.0 ng/mL

Recovery:
Testing was performed to determine trueness or percent recovery on the LIAISON® 25 TOTAL-D. Five (5) high concentration serum samples (spiked or endogenous) and five (5) low concentration serum samples were analyzed on the LIAISON® 25 TOTAL-D assay.

Recovery samples were then prepared by mixing defined ratios of the high and low samples and analyzing these in the LIAISON® 25 TOTAL-D assay. The obtained results were determined through calculation of % recovery for each dilution point:

% Recovery = (Observed conc. / Expected conc.)* 100

Expected conc. = conc. of High sample x % ratio used + Low sample x % ratio used

Each neat serum along with each blend was analyzed. The observed values were then compared to the expected values, based on the neat serum concentrations to determine the % recovery. The mean recovery is 96%.

Serum Samples	Defined Concentration	Expected ng/mL	Observed ng/mL	% Recovery
Serum High Sample 1 (HS1)	105.0			
2 HS1 : 1LS1		73.5	72.3	98%
1 HS1 : 1LS1		57.2	54.5	95%
1 HS1 : 2LS1		41.0	38.3	93%
Serum Low Sample 1 (LS1)	9.5			
Serum High Sample 2 (HS2)	95.5			
2 HS2 : 1LS2		67.5	63.4	94%
1 HS2 : 1LS2		53.1	49.0	92%
1 HS2 : 2LS2		38.6	35.9	93%
Serum Low Sample 2 (LS2)	10.6			
Serum High Sample 3 (HS3)	101.0			
2 HS3 : 1LS3		70.8	68.7	97%
1 HS3 : 1LS3		55.3	52.4	95%
1 HS3 : 2LS3		39.7	37.3	94%
Serum Low Sample 3 (LS3)	9.5			
Serum High Sample 4 (HS4)	58.5			
2 HS4 : 1LS4		44.4	43.7	98%
1 HS4 : 1LS4		37.1	36.4	98%
1 HS4 : 2LS4		29.8	29.3	98%
Serum Low Sample 4 (LS4)	15.7			
Serum High Sample 5 (HS5)	56.9			
2 HS5 : 1LS5		42.2	42.2	100%
1 HS5 : 1LS5		34.7	33.9	98%
1 HS5 : 2LS5		27.1	26.9	99%
Serum Low Sample 5 (LS5)	12.4			
			Mean Recovery	**96%**

Interfering Substances:
Vitamin D samples containing concentrations of 30 ng/mL and 60 ng/mL were spiked with hemoglobin, triglycerides, cholesterol, and bilirubin, uric acid, albumin,IgG, biotin, ascorbic acid, metoprolol, propanolol hydrochloride, furosemide, hydrochlorothiazide, paricalcital and doxercalciferol. Replicate samples (n=6 for each test and control sample) were tested and results were compared to control samples without the potentially interfering substances added. The highest concentrations at which no interference, or minimal interference (defined by the sponsor as ≤ 10% bias relative to the control) are shown below. The testing was based on CLSI EP7-A2.

Specimens That Are	**Demonstrate < 10% change in Results Up To**
Hemolyzed	200 mg/dL of hemoglobin
Lipemic	638 mg/dL of triglycerides
Icteric	40 mg/dL of conjugated bilirubin
Icteric	40 mg/dL of unconjugated bilirubin

Specimens That Contain	**Demonstrate < 10% change in Results Up To**
Cholesterol	350 mg/dL
Uric acid	20 mg/dL
Total Protein	12 g/dL
Biotin	0.1 mg/dL
Ascorbic Acid	6 mg/dL
Metoprolol	1.2 mg/dL
Propanolol hydrochloride	0.23 mg/dL
Furosemide	6 mg/dL
Hydrochlorothiazide	0.6 mg/dL
Paricalcital	0.012 µg/mL
Doxercalciferol	0.012 ug/mL

Cross-reactivity:
Cross-reactivity studies were performed as described in CLSI EP7-A2 using three serum pools at 25 OH D concentration levels of 15 ng/mL, 50 ng/mL, and 75 ng/mL. Data on the cross-reactivity of the antiserum used in this assay were obtained by spiking up to 100 ng/mL of the potential cross-reactant and assaying. The cross-reactivity of each compound, normalized to 25 OH Vitamin D_3, is listed below.

Steroid	**% Cross reactivity**
25 OH Vitamin D_3	100%
25 OH Vitamin D_2	93%
Vitamin D_3	3.6%
Vitamin D_2	1.9%
1,25 (OH)2 Vitamin D_3	17.1%
1,25 (OH)2 Vitamin D_2	27.1%
3-*epi*-25 OH Vitamin D_3	1.9%

Stability:
Shelf life stability studies were performed with controls and calibration verifiers and demonstrated that they are stable until the expiration date shown on the product labeling when stored as instructed. Controls and calibration verifiers are stable until the expiration date printed on the label when stored as directed. Once opened, controls and calibration verifiers are stable for 4 weeks when properly stored at 2-8°C between uses. Calibration curve stability and reagent open vial stability were performed and demonstrated that the calibration curve is stable for 7 days and open reagent vials are stable for 4 weeks when stored on board or at 2-8°C.

Traceability
The LIAISON® 25 TOTAL-D Calibrators, Controls and Calibration Verifiers are traceable to UV spectrophotometric analysis of an in-house standard preparation. The standard material used is a commercially available 25-Hydroxyvitamin D. The stock solution of 25 0H Vitamin D is then used to make calibrators by diluting into human serum.

Value assignment:
Concentrations of calibrators controls and calibration verifiers are assigned through an internal procedure. Master calibrators are prepared from a stock solution made from reference material whose concentration is determined spectrophotometrically. The master calibrators are then used to assign values to the kit calibrators, controls and calibration verifiers using a minimum of 3 LIAISON XL analyzers with at least 2 reagent lots. Each lot of controls and calibration verifiers are tested over several runs and the mean results are used to determine the target values.

25 TOTAL-D Calibrators
Level 1= 3.2 -4.8 ng/mL
Level 2= 70.0 – 80.0 ng/mL

25 TOTAL-D Controls have the following target ranges:
Level 1= 12.0 – 18.0 ng/mL
Level 2= 40.0 – 60.0 ng/mL

25 TOTAL-D Calibration Verifiers have the following target ranges:
Level 1= 8.5 – 11.5 ng/mL
Level 2= 27.0 – 33.0 ng/mL
Level 3= 59.0 – 71.0 ng/mL
Level 4= 108 - 122 ng/mL

CONCLUSION:
The material submitted in this premarket notification is complete and supports the basis for substantial equivalence to the LIAISON® 25 OH Vitamin D TOTAL assay (K112725).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 5, 2013

DiaSorin Inc.
C/O Mari Meyer
P. O. Box 285
1951 Northwestern Avenue
STILLWATER MN 55082-0285

Re: k132492
Trade Name: LIAISON® 25 TOTAL-D
LIAISON® 25 TOTAL-D Control Set
LIAISON® 25 TOTAL-D Calibration Verifiers
Regulation Number: 21 CFR §862.1825
Regulation Name: Vitamin D Test System
Regulatory Class: Class II
Product Codes: MRG, JJX
Dated: July 29, 2013
Received: August 9, 2013

Dear Ms. Meyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k132492

Device Name: LIAISON® 25 TOTAL-D, LIAISON® 25 TOTAL-D Control Set and LIAISON® 25 TOTAL-D Calibration Verifiers

The LIAISON® 25 TOTAL-D assay is a chemiluminescent immunoassay (CLIA) intended for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites in human serum, EDTA and Lithium heparin plasma. The LIAISON® 25 TOTAL-D assay is to be used as an aid in the assessment of vitamin D sufficiency in adults. The DiaSorin LIAISON® 25 TOTAL-D is intended to be used on the LIAISON® XL Analyzer.

The DiaSorin LIAISON® 25 TOTAL-D Control Set is intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® 25 TOTAL-D assay.

The DiaSorin LIAISON® 25 TOTAL-D Calibration Verifiers are assayed quality control materials intended for use in the quantitative verification of calibration and reportable range of the LIAISON® 25 TOTAL-D assay when performed on the LIAISON® XL Analyzer.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)__k132492_____